UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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| IN RE: FOSAMAX PRODUCTS LIABILITY LITIGATION | No. 06 MD 1789 (JFK) |
| This document relates to all actions. | **OPINION & ORDER** |

APPEARANCES

FOR PLAINTIFFS:
Brandon Bogle
Levin Papantonio, P.A.

FOR GENERIC DEFENDANTS:
Jonathan Price
Goodwin Procter, LLP

**John F. Keenan, United States District Judge:**

Before the Court is a motion to dismiss brought by the Generic Manufacturer Defendants ("Generic Defendants"). For the reasons that follow, Generic Defendants' motion is granted in part and denied in part.

## I. Background

Plaintiffs in this case were prescribed Fosamax and its generic equivalent, alendronate sodium, an oral bisphosphonate. This MDL involves claims that Fosamax, manufactured by Merck, or its generic equivalent, manufactured by the Generic Defendants, caused users to suffer from a condition known as osteonecrosis of the jaw ("ONJ"). Plaintiffs have asserted claims for failure to warn, negligence, design defect, breach of warranty, and fraud against both Merck and the Generic Defendants.

Generic Defendants have moved for judgment on the pleadings under Federal Rule of Civil Procedure 12(c). They argue that plaintiffs' state law tort claims are preempted by federal regulations applicable to generic drugs in light of the Supreme Court's recent decisions in PLIVA, Inc. v. Mensing (Mensing), 131 S. Ct. 2567 (2011) and Mutual Pharmaceutical Co. v. Bartlett, (Bartlett) 133 S. Ct. 2466 (2013). Alternatively, the Generic Defendants argue that the claims are inadequately pleaded.

## II. Discussion

### A. Standard of Review

A motion for judgment on the pleadings under Federal Rule of Civil Procedure 12(c) is governed by the same standard as a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). Cleveland v. Caplaw Enters., 448 F.3d 518, 521 (2d Cir. 2006). A motion to dismiss under 12(b)(6) may be granted only if, accepting all well-pleaded allegations in the complaint as true and viewing them in the light most favorable to the plaintiff, a court finds that the plaintiff has failed to set forth fair notice of what the claim is and the grounds upon which it rests. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A complaint must contain sufficient factual matter to "state a claim to relief that is plausible on its face."

Ashcroft v. Iqbal, 556 U.S. 662 (2009) (citing Twombly, 550 U.S. at 570). The plausibility standard requires that "the plaintiff plead[ ] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged" and demands "more than a sheer possibility that a defendant has acted unlawfully." Id. (citing Twombly, 550 U.S. at 556). Although a court must accept as true all factual allegations in a complaint, that tenet is "inapplicable to legal conclusions," and "[a] pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" Id. (citing Twombly, 550 U.S. at 555).

**B. Law of Preemption**

The Supremacy Clause of the United States Constitution provides that federal law "shall be the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. "Impossibility" preemption, which is at issue here, occurs when it is "impossible for a private party to comply with both state and federal requirements." Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995) (citation omitted); accord U.S. Smokeless Tobacco Mfg. Co., LLC v. City of New York, 703 F. Supp. 2d 329, 334 (S.D.N.Y. 2010). In other words, "[w]here state and federal law 'directly conflict,' state law must give way." Mensing, 131

S. Ct. at 2577 (quoting Wyeth v. Levine, 555 U.S. 555, 583 (2009) (Thomas, J., concurring in judgment)).

In Mensing, plaintiffs brought failure to warn claims under state law against several generic manufacturers of the drug metoclopramide , a drug commonly used to treat digestive tract problems. Mensing, 131 S. Ct. at 2573. Plaintiffs alleged that the generic manufacturers violated state tort laws by failing to change the labels for metoclopramide to adequately warn of the risk of a severe neurological disorder. Id. The applicable state tort laws required manufacturers that are "or should be aware of [their] product's danger to label that product in a way that renders it reasonably safe." Id. Under federal regulations, however, the generic manufacturers had a "duty of sameness" — that is, that "the warning labels of a brand-name drug and its generic copy must always be the same." Id. at 2574–75. The Supreme Court held that plaintiff's failure to warn claims under state law were preempted by federal law because "it was impossible for the Manufacturers to comply with both their state-law duty to change the label and their federal law duty to keep the label the same." Id. at 2578.

Under federal law, a generic drug manufacturer may obtain approval of a drug from the FDA simply by showing equivalence to a reference-listed drug that has already undergone clinical trials and gained approval from the FDA. 21 U.S.C.

§ 355(j)(2)(A). A generic drug manufacturer has the responsibility to ensure that the labeling for the generic drug is the same as the labeling approved for the listed drug. 21 U.S.C. §§ 355(j)(2)(A)(v) & (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8) & 317.127(a)(7). The FDA interprets these regulations as imposing an ongoing duty for generic manufacturers to update their product labels to ensure the sameness of the generic and name-brand drug labels. Mensing, 131 S. Ct. at 2575; 57 Fed. Reg. 17961 (1992) ("Abbreviated New Drug Application (ANDA) product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval").

In Bartlett, the issue presented was whether state law design defect claims are also preempted under Mensing. The plaintiff, Bartlett suffered tragic side effects from the generic form of a nonsteroidal anti-inflammatory called sulindac. She prevailed in district court on a design defect claim, and the First Circuit affirmed the judgment. In reversing the First Circuit, the Supreme Court held that "it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label. Accordingly, the state law is pre-empted." Bartlett, 131 S. Ct. at 2473.

Generic Defendants have based their motion to dismiss largely on the Supreme Court's preemption jurisprudence as set forth in Mensing and Bartlett. The Court will now explore whether how these cases implicated plaintiffs' claims against Generic Manufacturers.

**C. Failure to Warn**

Plaintiffs concede preemption on many of their failure to warn claims, but argue that Mensing merely "narrow[s] the field of claims that can fairly be assured under failure to warn theories." According to plaintiffs, "it is clear that claims that generic manufacturers should have unilaterally strengthened their warnings are preempted," but other claims under failure to warn survive. Specifically, plaintiffs contend that the following two categories of failure to warn claims are not preempted: (1) alleged failure to timely update its labels, and (2) duty to communicate warnings to plaintiffs and their physicians. The Court will turn its analysis to whether these narrow claims of failure to warn are preempted by federal law.

**i. "Failure to Update"**

As an initial matter, plaintiffs contend that "many of the generic defendants have already made a binding judicial admission that they did not timely add the ONJ information Merck first included in its label in March of 2010." According to plaintiffs, Defendants Caraco and Sun Pharmaceuticals did not

employ the updated label for a year after Merck issued it. Plaintiffs make similar allegations regarding Mylan, Aurobindo, Northstar, and Watson. The Generic Defendants ardently reject the notion that they admitted to a delay in updating the labels, adding, "nor has there been any regulatory or judicial finding that any Generic Defendants' label revisions were untimely."

The Court need not reach the question of whether any alleged "admissions" of delay by Generic Defendants are "binding." Rather, it is sufficient for the Court to note that plaintiffs have adequately pleaded that some Generic Defendants' delay in updating their labels was unreasonable. Therefore, the relevant issue here is whether these "failure to update" claims are preempted.

Although courts in other circuits have considered this issue, it is one of first impression for this Circuit. This Court joins the majority of other jurisdictions in finding that "failure to update" claims against the Generic Defendants are not preempted. Although Generic Defendants were preempted by federal law from including additional warnings, they were required under federal law to ensure that their labeling reflected FDA-approved warnings for the name-brand drug.

Fulgenzi v. PLIVA, Inc., 711 F.3d 578 (6th Cir. 2013) supports this conclusion. In that case, a brand-name drug manufacturer had updated its warning label in July 2004 to

include the risks of long-term use of the drug. Id. at 580. The plaintiff took the generic version of the drug for extended periods on two different occasions — between September and November 2004, and then for over a year in 2006 and 2007. Id. The generic drug manufacturer did not update its warning label to match the label of the brand-name drug during the entire time the plaintiff was taking the drug. Id. at 580-82. The plaintiff developed serious complications and she sued the generic drug manufacturer under Ohio tort law, claiming the generic drug manufacturer's failure to update its warning label "'rendered its warnings inadequate under Ohio law'" Id. The Sixth Circuit concluded that the preemption doctrine did not bar the plaintiff's claim. Id. ("In our case, not only could PLIVA have independently updated its labeling to match that of the branded manufacturer through the CBE process, see Mensing, 131 S. Ct. at 2575, but it had a federal duty to do so, 21 C.F.R. § 314.150(b)(10).").

In this case, as in Fulgenzi, it was possible for the Generic Defendants to comply with their federal duty to match their labels to the Fosamax label, while also satisfying their state tort law duty to adequately warn the consumers of alendronate sodium. Indeed, its obligations under federal law were coextensive with state law requirements.

Various state and federal trial courts have reached the same conclusion, based on comparable fact patterns. See Phelps v. Wyeth, Inc., Pliva, Inc., et al., No. 09 Civ. 06, 2013 WL 1403060 at. *3 (D. Or., Apr. 2, 2013) ("Unlike the failure to warn claim in Mensing, plaintiffs do not claim that Pliva was required to use a different or stronger warning label; they merely claim that, under Oregon law, Pliva was negligent by failing to update its label to match the name-brand label — a requirement that is consistent with the FDCA. Thus, because plaintiffs' state-law claim does not make it impossible for Pliva to comply with federal law, no conflict exists and preemption is not warranted"); Johnson v. Teva Pharmaceuticals USA, Inc, 10 CV 404 2012 WL 1866839 at *3 (W.D. La., May 21, 2012) ("[I]mpossibility preemption would not apply to any requirement . . . that the Generic Defendants update their product labels to reflect labeling changes made by the brand name manufacturer"); Cooper v. Wyeth, Inc, 09–929, 2012 WL 733846 at *4 (M.D. La., Mar. 6, 2012); Couick v. Wyeth, Inc., 09–cv–210, 2012 WL 79670 at*5 (W.D.N.C., Jan. 11, 2012); Del Valle v. PLIVA, Inc., 11–113, 2011 WL 7168620 at *5 (S.D. Tex., Dec. 21, 2011) (generic drug manufacturers' failure to update their labels, "after the brand named manufacturers enhanced their warning labels in 2004, might preclude the application of conflict pre-emption, but only as to the labeling information

added by the brand named manufacturers in 2004"); In re Reglan Litigation, No. 289, 2012 WL 1613329 (Super. Ct. Atlantic County, N.J. 2012); Fisher v. Pelstring, 817 F. Supp. 2d 791, 805 (D.S.C. 2011).

Generic Defendants have argued that since there is a federal statute specifically excluding private causes of action for violations of FDA regulations, 21 U.S.C. § 337(a), state tort suits premised on violations of federal law are impliedly preempted. Buckman Co. v. Plaintiffs' Legal Cmte., 531 U.S. 341, 348 (2001) (holding that state law "fraud on the FDA" claims were impliedly preempted by the Food, Drug, and Cosmetic Act). However, these failure to update claims are not premised on federal law, but rather on an independent state duty. As such, the federal duty of sameness is not "a critical element" in plaintiffs' cases. Buckman, 531 U.S. at 353 ("[W]ere plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case."). The theory of these cases would work "equally well against a branded-drug manufacturer, or a generic-drug manufacturer whose branded counterpart had not updated its warning." Fulgenzi, 711 F.3d at 587.

It is important to emphasize, however, that consistent with Mensing, the duty of the Generic Defendants extends only to their alleged failure to update the label within a reasonable time after Merck did. Plaintiffs cannot claim that the Generic Defendants should have included additional warnings; any such allegations are preempted under Mensing. Instead, plaintiffs are left to argue only that the Generic Defendants' warning was inadequate to the extent that it did not include the language contained in the updated label.

**ii. "Failure To Communicate"**

Plaintiffs also assert that the Generic Defendants may also be held liable for failing to communicate the 2003 and 2004 labeling changes to physicians and consumers through the use of "Dear Doctor" letters or by other methods. Plaintiffs argue that Mensing held only that generic manufacturers could not send "Dear Doctor" letters that contained new or additional warnings, and the Supreme Court did not consider whether a generic manufacturer could use such letters or other methods to apprise health care professionals of information appearing in approved labeling.

Plaintiffs' argument is incorrect. In fact, the Supreme Court in Mensing decision squarely foreclosed this argument:

> A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling. Moreover, if generic drug

> manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly "misleading." . . . Accordingly, we conclude that federal law did not permit the Manufacturers to issue additional warnings through Dear Doctor letters.

Mensing, 131 S. Ct. at 2576 (emphasis added). As stated by one district court, "labeling is so broadly defined that it encompasses nearly every form of communication with medical professionals . . . . Simply put, the generic drug defendants are not allowed to alter the labeling adopted by the brand manufacturers in any way." Del Valle v. PLIVA, Inc., 2011 WL 7168620, at *6 (S.D. Tex. Dec. 21, 2011) (citing Mensing, 131 S. Ct. at 2576 and 21 C.F.R. § 202.1 (l)(2)).

This Court joins the majority of other courts to consider this issue in holding that any claims stemming from the generic defendants' alleged failure to communicate additional warnings through some method other than their package inserts are preempted. Demahy v. Schwarz Pharma, 702 F.3d 177, 185 (5th Cir. 2012) ("failure to warn claims that did not require the manufacturer to add to or differ its warnings from those appearing in the label of its brand-name counterpart" are still preempted); Strayhorn v. Wyeth Pharm., Inc., 887 F. Supp. 2d 799, 819 (W.D. Tenn. 2012) ("Plaintiffs' assertion that the Generic Defendants could have sent Dear Doctor letters or other communications to physicians or patients is also preempted");

Moore v. Mylan Inc., 840 F. Supp. 2d 1337, 1349 n.11 (N.D. Ga. 2012); Guarino v. Wyeth LLC, 823 F. Supp. 2d 1289, 1292–93 (M.D. Fla. 2011).

**D. Design Defect**

In light of the Supreme Court's recent decision in Mutual Pharmaceutical Co. v. Bartlett (Bartlett), which addressed design defect claims post-Pliva, the parties submitted supplemental briefing. While Generic Defendants contend that Bartlett compels the finding that all design defect claims are preempted, the plaintiffs argue that none of their design defect claims are preempted, despite the holding in Bartlett.

Specifically, plaintiffs proffer that the decision in Bartlett turned on New Hampshire law, which strictly applies comment k to § 402A of the Restatement (Second) of Torts. Therefore, according to plaintiffs, Bartlett does not "provide a basis for wholesale dismissal of plaintiffs' design defect claims."

Plaintiffs' attempt to evade preemption on their design defect claims falls flat. Bartlett does not apply only to design defect claims predicated on label inadequacies, as plaintiffs argue. The Supreme Court explicitly discusses chemical composition:

> In the present case, however, redesign was not possible for two reasons. First, the FDCA requires a generic drug to have the same active ingredients, route of administration,

> dosage, strength, and labeling as the brand-name drug on which it is based. . . . Indeed, were Mutual to change the composition of its sulindac, the altered chemical would be a new drug that would require its own NDA to be marketed in interstate commerce. Second, because of sulindac's simple composition, the drug is chemically incapable of being redesigned.

131 S. Ct. at 2475. The Supreme Court's logic applies with equal force here. The Generic manufacturers could not have changed the chemical composition of the generic forms of Fosamax without being subjected to FDA procedures for new drugs.

In plaintiffs' original opposition brief, they explicitly disclaimed a label change as the possible solution to the alleged design defect, choosing to focus only on the claim that the risks of the drugs outweighed the benefits. (Pl. Opp. at 8. ("It is true that in other cases, some plaintiffs have alleged that part of what makes a product defective by design is that the "design" or the product did not include appropriate warnings. These plaintiffs . . . are guilty of sloppy draftsmanship. The plaintiffs here, however . . . [allege] true design claims that . . . the risks of the defendants' drug outweigh the benefits of taking the drug.")). Bartlett explicitly addressed this claim and found it to be preempted.

Plaintiffs try to rescue their design defect claims by refusing to specify what they believe the generics should have done differently with respect to the design of alendronate sodium. In light of this omission, the Court is left to

speculate; all the potential claims the Court can imagine have been preempted by Bartlett. As discussed above, Bartlett squarely preempts design defect claims where the proposed solution is a label change, as well as design defect claims based upon chemical composition flaws. It also found preempted the possibility of design defect claims based on a generic defendant's failure to stop selling the product. Since no other way that Generic Defendants could comply with their federal and state duties has been proffered, impossibility preemption applies.

**III. Conclusion**

For the reasons stated above, the Generic Defendants' motion to dismiss is granted with respect to the design defect claims. The motion to dismiss is also granted as to the failure to warn claims, except to the extent that plaintiffs may claim that the Generic Defendants failed to timely update their labels after Merck updated the Fosamax label.

SO ORDERED.

Dated: New York, New York
August 14, 2013

John F. Keenan
John F. Keenan
United States District Judge